

REMARKS/ARGUMENTS

Claims 35, 37-42, 44-55, and 57 remain pending, and claims 35, 48, and 51 are revised. Support for these amendments is found, for example, at page 11, lines 10-12, of the specification as filed. Applicant respectfully requests entry of the foregoing amendments and reconsideration of the application in view of the following remarks.

Applicant thanks Examiner Channavajjala for the courtesies extended to Applicant's representatives during the interview held on November 30, 2004. Applicant believes the interview was helpful in advancing prosecution of the application. The substance of the interview is summarized below, as required by MPEP § 713.04.

As noted on the Interview Summary, the novelty and non-obviousness of the invention was discussed at the interview. In particular, Applicant's representatives pointed out that it was Applicant who first recognized that isovaleramide, isovaleric acid, and the other related compounds recited in the claims have a short half-life *in vivo*. This is set forth, for example, at pages 2 and 5 of the specification as filed. Prior to this discovery, there was no motivation to provide the recited compounds in a sustained-release composition. Thus, the prior knowledge of isovaleramide compositions and sustained-release compositions of other drugs does not render obvious the claimed sustained-release isovaleramide compositions, because there was no reason for those skilled in the art to formulate isovaleramide into a sustained-release composition. It is only the present invention that provides that motivation, by teaching the short half-life of the claimed compounds *in vivo*.

The Hsiao (USPN 4,571,333) and Artman (WO 99/44623) references cited in the Office Action were discussed at the interview. Hsiao is directed to sustained-release formulations of naproxen, an NSAID. Artman is directed to combination therapies comprising the administration

of isovaleramide (or related compounds) and an NSAID. Neither reference teaches a sustained-release isovaleramide composition. As agreed at the interview, this combination of references does not establish a *prima facie* case of obviousness of the instant claims.

First, these references do not provide any motivation to provide isovaleramide (or related compounds) in a sustained-release formulation. Without the knowledge provided in the instant application that the isovaleramide compounds have a short half-life *in vivo*, it would not have been obvious to prepare the isovaleramide compositions disclosed in Artman in a sustained-release formulation, even though Hsiao shows a sustained-release formulation of another drug.

Moreover, while the Office Action asserts that it would have been obvious to add an isovaleramide compound to the tablets of Hsiao, Hsiao teaches away from such a modification of its invention. As taught at column 4, lines 9-29, the objective of Hsiao is to provide a maximum amount of naproxen (500-1200 mg) in a tablet with minimum bulk. To achieve this goal, the tablets of Hsiao must contain from 81-96% by weight naproxen. This simply does not leave room for a therapeutically effective amount of the active compounds of the present invention.

Applicant believes that the 30-90% w/w amount of active compound and gelling agent recited in the previous claims left no question that compositions based on Hsiao are excluded from the claims, because a composition cannot comprise both 81-96% naproxen and 30-90% isovaleramide compound and gelling agent. During the interview, the Examiner indicated that a recitation of active compound amount alone might be preferable. Thus, Applicant has amended independent claims 31, 48 and 51 to recite that the composition comprises from 40-70% by weight of the active compound, as taught at page 11, lines 10-12 of the specification. As with the previous language, it would be impossible to formulate a composition that comprises both 81-96% naproxen, as required by Hsiao, and 40-70% of the presently claimed active compounds.

In view of the foregoing, Applicant respectfully urges the Examiner to reconsider and withdraw the rejection based on Hsiao and Artman.

Applicant believes that the application is in condition for allowance, and an early notice to that effect is earnestly solicited. Should there be any questions regarding this submission, or should any issues remain, the Examiner is invited to contact the undersigned by telephone in order to further advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 CFR §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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